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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,043	02/22/2002	Oliver Yoa-Pu Hu	39297-174169	8602
23639	7590	04/29/2005	EXAMINER	
BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO CENTER 18 FLOOR SAN FRANCISCO, CA 94111-4067			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,043

Applicant(s)

HU ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-25 is/are pending in the application.
- 4a) Of the above claim(s) 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-16,24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Applicants' Response filed March 10, 2004 to the Restriction requirement is acknowledged. Applicants elected Group I, drawn to CYP3A inhibitors alone and in combination with a drug, and methods of use thereof. Further, Applicants elected the single disclosed species swertiamarin.

Accordingly, claims 17-23, drawn to non-elected inventions, are withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. Claims 2 and 4 are canceled. New claims 24 and 25 were presented in an Amendment filed September 29, 2003 in response to the first Office Action. Claims 1, 3, 5-16, 24 and 25 are presently under consideration, wherein swertiamarin is the cytochrome P450 3A (CYP3A) inhibitor initially under consideration.

The disclosure is objected to for the following informalities: Claim 9 is dependent from claim 9. Claim 25 is dependent from claim 25.

Appropriate correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5-9 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 43, 49 and 51 of copending Application No. 10/079416. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3, 5-9 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/948206. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3 and 6-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 1 is written as a compound claim. It is unclear whether or not claims 7-15 are intended to be composition claims or method of use claims.

Clarification is required.

Claims 7-9 and 12 recite an active step for which there is insufficient antecedent basis in the independent claim from which they depend.

Only claim 6 is a proper composition claim. Only claim 16 is a proper method claim.

Claims 12-15 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicants are required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Claims 12-15 do not further limit the subject matter of claim 1, in that claim 1 is directed to compounds.

Applicants' arguments with respect to claim 1-15 that were rejected in the first Office Action under 35 U.S.C. 103 as being unpatentable over Edgar et al., Wachter et al., and Benet et al. (AE and AF), have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamahara et al., Journal of Ethnopharmacology (abstract).

Yamahara teaches the compound swertiamarin as prepared in a pharmaceutical composition for oral administration.

Claims 16, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention. The claims are directed to the treatment of any intestinal or hepatic cancer. The specification provides support for the ability of swertiamarin to inhibit CYP3A activity.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treatment a patient having any intestinal or hepatic cancer comprising administering swertiamarin.

The relative skill of those in the art is generally that of a Ph.D. or M.D. having expertise in the field of oncology.

Each particular hepatic or intestinal cancer has its own specific characteristics and etiology. The broad recitation "treating patient with intestinal or hepatic cancer" is inclusive of many pathologies that presently have no established successful therapies.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of any cancer of hepatic or intestinal origin.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples wherein swertiamarin is administered to treat cancer.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular type of intestinal or hepatic cancer would be treated through administration of swertiamarin. The skilled artisan would expect the administration of swertiamarin in the treatment of a particular cancer to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for use. The instant specification sets forth no such understanding or any criteria for extrapolating beyond the inhibition of CYP3A. No

direction is provided to treat any cancer comprising administering swertiamarin. Absent reasonable *a priori* expectations of success for using a particular chemotherapeutic agent, one skilled in the oncology art would have to test extensively many neoplastic conditions to discover which responds to swertiamarin. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Mondays to Fridays from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at telephone number 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

**PHYLLIS SPIVACK
PRIMARY EXAMINER**

April 26, 2005